



**PILA PHARMA AB**

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## **PILA PHARMA ANNOUNCES INITIATION OF STUDY IN PRECLINICAL RESEARCH COLLABORATION IN CARDIOVASCULAR DISEASE**

**PILA PHARMA AB (publ) (“PILA PHARMA” or the “Company”) today announces the initiation of the study associated to the co-sponsorship of the research collaboration with the Research Group of Professor [Dick Wågsäter](#), Uppsala University, Sweden (the “Research Group”). The aim is to complete initial investigations on the effect of PILA PHARMA’s lead molecule, XEN-D0501, on Abdominal Aorta Aneurism growth in mice.**

The hypothesis is that XEN-D0501 may reduce the chronic inflammation that leads to cardiovascular disease including aorta dilatation. Thus, XEN-D0501 could potentially prevent the lethal end-stage development of Abdominal Aorta Aneurism (AAA).

As previously described, PILA PHARMA will take on the active co-sponsor role to allow for progression of this important work. As previously disclosed, the results of the studies will be split in the sense that the Research Group gets the publication right (after patenting) and Prof. Dick Wågsäter has agreed to transfer to PILA PHARMA the patent rights against that PILA PHARMA sponsors any resulting patents.

The aim of the collaboration is to establish a pre-clinical proof-of-concept of an effect of XEN-D0501, a TRPV1-antagonist, on preventing progression of AAA in mice.

**CSO Dorte X. Gram comments:** *“Professor Wågsäter has informed me that the mouse study has been started. The first 48 hours after inducing the artificial aneurisms are always critical but nothing drastic had occurred and we can now await the 28 days treatment with XEN-D0501 or placebo to complete. If the results of this mouse study are positive, i.e. if XEN-D0501 then is able to prevent aneurysm and/or limit aneurism rupture development, it could open up to assessing the effect of XEN-D0501 in humans with AAA”.*

**CEO Gustav H. Gram further comments:**

*I’m happy that we’ve been able to progress so fast that the first mice have now been dosed. As we previously mentioned, by investigating how XEN-D0501 can affect AAA development in mice, we want to understand the cardiometabolic properties of our molecule better. Having a strong beneficial cardiovascular profile, can be of real benefit when determining the potential value of our molecule. As we know by now, cardiovascular diseases are major causes of death globally, with strong traces to the global obesity pandemic, and AAA specifically is one of the comorbidities that kills – approximately 1% of all men above the age of 65 every year. No preventive pharmacological treatments are available. Thus we believe in the possibility of adding strong value if we can showcase positive results.*

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PILA PHARMA's share ticker PILA is subject to trade on Nasdaq First North Growth Market, Sweden with Aqurat Fondkommission AB as Certified Adviser. Contact: M: [ca@aquarat.se](mailto:ca@aquarat.se), T: +46 (0)8 684 05 800

### **About PILA PHARMA AB (Publ)**

PILA PHARMA is a Swedish biotech company based in Malmö, Sweden. The aim of the company is to develop TRPV1 antagonists as a novel treatment of type 2 diabetes and potentially of other diseases with an inflammatory background. The Company owns a TRPV1 asset with data and chemical entities including the development candidate XEN-D0501. Further, the Company owns use-patents covering the use of TRPV1-antagonists as treatment of obesity and diabetes and intends to submit further patents regarding the synthesis, formulation, or use of XEN-D0501 or back-up compounds. In July 2022, the Company was awarded orphan drug designation ("Orphan drug designation") for XEN-D0501 as a treatment for erythromelalgia. PILA PHARMA currently focuses on 3 projects within Type-2 Diabetes, Erythromelalgia, and Abdominal Aorta Aneurism.

### **About XEN-D0501 and TRPV1 antagonists**

XEN-D0501 is a selective, synthetic potent small molecule TRPV1 antagonist that was in-licensed in 2016. TRPV1 antagonists that down-regulate neurogenic inflammation, has demonstrated applications across pain and inflammatory diseases and potentially plays a role in diabetes and potentially other metabolic disorders like obesity. Prior to in-licensing, XEN-D0501 had been found to have a good safety profile in other (non-diabetic) patient groups. PILA PHARMA has to date completed two phase 2a clinical trials (PP-CT01 and PP-CT02), that both demonstrated that XEN-D0501 is well tolerated by in people living with obesity and type 2 diabetes. Further, PP-CT02, demonstrated that XEN-D0501 (administered as 4 mg bi-daily for 28 days) - with statistical significance versus placebo - enhanced the endogenous insulin response to oral glucose. Furthermore, ANP, a cardiovascular biomarker for heart failure, was highly statistically significantly reduced. During 2023 the Company could report very good tolerability of XEN-D0501 following 13 weeks administration of very high doses in 2 animal species, and XEN-D0501 can thus progress into longer clinical trials. Currently, a scientific advice regarding the study design of the next clinical phase 2a trial, PP-CT03, is being prepared and will be followed by a clinical trial submission in the UK. The objective of the study is to identify the maximal tolerable dose of XEN-D0501 in people living with obesity and type 2 diabetes and to evaluate the safety profile following 3 months chronic treatment. In addition to the safety assessment, PP-CT03 will also include sufficient participants that should allow for efficacy readouts on reduction of body weight.

### **About Diabetes and Obesity**

Diabetes is a globally spanning pandemic with a staggering estimated prevalence of more than 537 million people living with diabetes corresponding to approximately 8-10% of the global adult population. Among these, its estimated that more than approximately 90 % of all



diabetics suffer from type-2 diabetes, whilst approximately less than 10% suffers from type-1 diabetes. Despite recent therapeutic advances, large and growing unmet needs exist both from efficacy, safety, and accessibility standpoints.

Obesity is an even larger pandemic with estimates of more than 1 billion people suffering from it in 2025. It is most often preceding the development of type 2 diabetes and is a serious risk-factor for not only developing type 2 diabetes but also co-morbidities resulting in "whole body dysfunction" and subsequent development of several diseases. The accumulated effect is a year-long reduction in quality of life for obese people with or without diabetes. Obesity leads to an increased risk of developing cardiovascular disease that eventually results in premature death and shortening of life duration. Recent advances by "Big Pharma" in the development of effective anti-obesity drugs, has proven that pharmacological weight management is possible and leads to obvious quality-of-life and longevity benefits for people living with obesity. Even long-term, public health costs are expected to be reduced if the clinically negative effects of the obesity pandemic are limited. This has sparked a general interest in future potential oral treatments that can meet the accessibility criteria needed to stimulate growing demand, and several acquisitions have been done in the obesity segment recently.

#### **About Erythromelalgia**

Erythromelalgia is a rare disease where neurogenic inflammation plays a role in the development of symptoms. The disease can cause near-constant or episodic pain (ranging from mild tingling to severe burning sensations), and redness to extremities. It most commonly affects the feet but may also occur in the hands, face, or other parts of the body with both nerves and blood vessels involved. Symptoms are frequently managed through avoidance of pain triggers. The disorder can be extremely debilitating, with a significant negative impact on quality of life and with potential to impact mortality rates among young people and the suicide rates among adults. Pila Pharma aims to conduct a small proof of concept study in persons with erythromelalgia to demonstrate an effect of XEN-D0501 on reducing perceived pain during "flare ups". There are no current treatments available to patients. PILA PHARMA has made a development plan for this project.

#### **About Abdominal Aorta Aneurism**

Abdominal Aorta Aneurism is a cardiovascular disease with 'ballooning' of the lower part of the main artery of the body, aorta. The cause is unknown, but risk factors are atherosclerosis, high blood pressure, cardiovascular inflammation and infection as well as trauma. It affects millions of people globally and accounts for the death of 1% of men over the age of 65. It develops gradually over several years up to a dilatation of more than 3mm in diameter when surgery to insert a stent to prevent rupture is then the only treatment option, which is both expensive and with possibility for complications. Currently no preventive treatment is available. In November 2023 a research collaboration was entered with Professor Dick Wågsäter from Uppsala University for investigating the effect of XEN-D0501 on Abdominal Aorta Aneurism growth in mice. In November 2024, PILA PHARMA decided to co-sponsor the mouse studies to ease the progression of the preclinical studies.